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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,411	02/12/2004	Charles Gordon	5943-00300	4318

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EXAMINER

SCHILLINGER, ANN M

ART UNIT	PAPER NUMBER
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3738

MAIL DATE	DELIVERY MODE
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09/24/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/777,411

Applicant(s)

GORDON ET AL.

Examiner

Ann Schillinger

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 June 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15-18, 21-24, 27-31 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Sertich (U.S. Pat. No. 5,800,550). Sertich discloses the following of claim 15: an intervertebral implant for a human spine, comprising: a cage element (30) comprising a superior surface (32) and an inferior surface (34), wherein the inferior surface of the cage element is configured to engage a first vertebra of the human spine (col. 2, lines 35-37; see Figure 2), and wherein the superior surface of the cage element comprises a first opening (54 or 56); an insert (70) comprising a superior surface (74) and an inferior surface (72), wherein the insert is configured to be positioned at least partially in the cage element (see Figure 1A); and an expansion member (98, 114, 118) configured to be advanced through an opening (44) in a side of the cage element to expand the intervertebral implant by elevating the insert and moving a portion of the insert through the opening in the superior surface of the cage element, thereby increasing a height of the intervertebral implant and allowing the superior surface of the insert to engage the second vertebra of the human spine (col. 7, lines 34-47; see Figures 2, 9).

Sertich discloses the following of claim 16: the intervertebral implant of claim 15, wherein intervertebral implant is configured such that the direction of movement of

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the expansion member (horizontal) is substantially perpendicular to the direction of movement of the insert (vertical; see Figure 1A).

Sertich discloses the following of claim 17: the intervertebral implant of claim 15, wherein the expansion member is configured to be advanced between an interior surface of the cage element and the inferior surface of the insert (see Figure 1A).

Sertich discloses the following of claim 18: the intervertebral implant of claim 15, wherein the superior surface of the insert comprises osteoconductive mesh structure (col. 4, lines 17-21).

Sertich discloses the following of claim 21: an intervertebral implant for a human spine, comprising: a cage element (30) comprising a superior surface (32) and an inferior surface (34), wherein the inferior surface of the cage element is configured to engage a first vertebra of the human spine (col. 2, lines 35-37; see Figure 2), and wherein the superior surface of the cage element comprises an opening (54 or 56); an insert (70) comprising a superior surface (74) and an inferior surface (72), wherein the insert is configured to be positioned in the cage element such that the inferior surface of the insert is inside of the cage element and the superior surface of the insert is outside of the cage element (see Figure 1A); and an expansion member (98, 114, 118) configured to be advanced through an opening (44) in a side of the cage element to elevate at least a portion of the insert through the opening in the superior surface of the cage element, thereby increasing a height of the intervertebral implant and allowing the superior surface of the insert to engage the second vertebra of the human spine (col. 7, lines 34-47; see Figures 2, 9).

Sertich discloses the following of claim 22: the intervertebral implant of claim 21, wherein the intervertebral implant is configured such that the direction of movement of the expansion member (horizontal) is substantially perpendicular to the direction of movement of the insert (vertical; see Figure 1A).

Sertich discloses the following of claim 23: the intervertebral implant of claim 21, wherein the expansion member is configured to be advanced between an interior surface of the cage element and the inferior surface of the insert (see Figure 1A).

Sertich discloses the following of claim 24: the intervertebral implant of claim 21, wherein the superior surface of the insert comprises osteoconductive mesh structure (col. 4, lines 17-21).

Sertich discloses the following of claim 27: an intervertebral implant for a human spine, comprising: a cage element (30) with a superior surface (32) and an inferior surface (34), wherein the inferior surface of the cage element comprises a first opening (58 or 60) and the superior surface of the cage element comprises a second opening (54 or 56); a first insert (element 70 that is located at element 58 or 60) configured to be positioned in the cage element proximate the first opening; a second insert (element 70 that is located at element 54 or 56) configured to be positioned in the cage element proximate the second opening (see Figure 1A); and an expansion member (98, 114, 118) configured to be advanced through a third opening (44) in the cage element to expand the intervertebral implant by engaging the first insert and the second insert after the intervertebral implant is positioned between a first vertebra and a second vertebra of the human spine, wherein engaging the first insert comprises moving a portion of the first insert through the first opening of the cage element such that an inferior surface of the

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first insert engages the first vertebra of the human spine, and wherein engaging the second insert comprises moving a portion of the second insert through the second opening of the cage element such that a superior surface of the second insert engages the second vertebra of the human spine (col. 7, lines 34-47; see Figures 2, 9).

Sertich discloses the following of claim 28: the intervertebral implant of claim 27, wherein intervertebral implant is configured such that the direction of movement of the expansion member (horizontal) is substantially perpendicular to the direction of movement of the first insert and the second insert (vertical; see Figure 1A).

Sertich discloses the following of claim 29: the intervertebral implant of claim 27, wherein the expansion member is configured to be advanced between a superior surface of the first insert (72 of lower element 70) and an inferior surface of the second insert (72 of upper element 70).

Sertich discloses the limitations of claims 30 and 31 in col. 4, lines 17-21.

Sertich discloses the following of claim 33: the intervertebral implant of claim 27, wherein expanding the intervertebral implant comprises increasing a height of the intervertebral implant (col. 7, lines 34-47).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 19, 25, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sertich in view of Larsen et al. (U.S. Pat. No. 5,782,832). Sertich discloses the invention substantially as claimed, however, Sertich does not disclose a raised portion of the inferior surface of the cage that will inhibit backout of the expansion member. Larsen et al. teaches such a projection in col. 8, lines 8-29 for the purpose of traversing movement within the interior of the implant. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a raised portion of the inferior surface of the cage in order to inhibit backout of the expansion member by traversing movement within the interior of the implant.

Claims 20, 26, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sertich in view of Fleischmann et al. (U.S. Pat. No. 6,375,682). Sertich discloses the invention substantially as claimed, however, Sertich does not disclose increasing the expansion member's height to increase the implant's height. Fleischmann et al. teaches this in col. 1, lines 8-24 and in col. 8 for the purpose of adjusting the height to the desired intervertebral spacing of the spine. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to increase the expansion member's height to increase the implant's height in order to adjust the height to the desired intervertebral spacing of the spine.

Response to Arguments

In view of the amendments to the specification and claims 20, 26, and 34, the objections to the drawings and the 35 USC § 112 claim rejections are withdrawn.

Applicant's arguments filed 6/21/2007 have been fully considered but they are not persuasive. The Applicant contends that the Sertich and the Larsen et al. references do

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not disclose the featured limitations claimed in the application. However, claims in a pending application should be given their broadest, reasonable interpretation. In re Pearson, 181 USPQ 641 (CCPA 1974). Regarding claims 15, 16, 21, 22, 27, and 28, the Applicant contends that the Sertich reference does not disclose an "expansion member." However, the expansion member cited in the previous office action and above has platforms that contribute to the expansion of the pegs in a perpendicular into the adjacent vertebrae. Also, regarding claims 17, 23, and 29, the expansion member progresses forward between the superior and inferior surfaces as it is turned. Please see col. 7, lines 5-48 for further clarification. The Applicant also contends that the Sertich reference discloses no osteoconductive mesh structure. However col. 4, lines 17-24 discloses the use of autologous cancellous bone, which inherently is a mesh structure that will promote bone ingrowth and fusion. Regarding claim 33, the Applicant contends that the Sertich reference does not disclose an intervertebral implant that increases in height. However, Sertich discloses how the pegs of the intervertebral implant expand in height in col. 7, lines 34-47.

Regarding claims 19, 25, and 32, the Applicant contends that the Sertich reference in combination with the Larsen et al. reference does not teach an interior surface element with a raised portion to inhibit backout of the expansion member. However, Figures 21-24 and col. 8, lines 8-29 discloses the elements that meet these limitations. Camming blocks 412 and 416 work in conjunction with elements 422 and 410 to hold the implant in place.

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Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571) 272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ann Schillinger
September 9, 2007

A. Stewart
ALVIN J. STEWART
PRIMARY EXAMINER